



June 20, 2011

Via Email

Dr. Angela Nugent
Designated Federal Officer, EPA
Science Advisory Board (1400R)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

RE: US EPA Science Advisory Board Dioxin Review Panel's Report, *SAB Review of EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments*

Dear Dr. Nugent:

The American Chemistry Council (ACC) appreciated the opportunity to participate in the Environmental Protection Agency's (EPA) Charter Scientific Advisory Board (Charter SAB) review of the report prepared by its Dioxin Review Panel (Panel). At the June 6 public meeting and teleconference at which that review was conducted, the Charter SAB voted unanimously to charge the Panel with making several important revisions to its draft report, and to have the four lead reviewers from the Charter SAB evaluate those revisions to ensure that they are consistent with the Chartered SAB's objectives. However, at the end of the June 6 meeting, there was no effort to summarize and clarify, in light of the various comments of individual Charter SAB members on the topics at issue, the Charter SAB's precise expectations. Therefore, in order to ensure that the final SAB report to EPA fully captures the numerous scientific deficiencies noted by the Charter SAB, ACC requests that the Panel be given clear direction by the Charter SAB regarding the revisions to be made to the Panel's draft report.

To that end, ACC offers the following summary of revisions that the Charter SAB appeared to be calling for, and requests that this summary be provided to both the Charter SAB and the Panel for their consideration as these revisions are made and reviewed prior to finalizing the report. Clarity in the direction given to the Panel as to the revisions to be made in the SAB report will hopefully achieve a fundamental objective raised by several Charter SAB members, i.e., because the recommendations in the report will go to EPA for action on its part, it is important that those recommendations be clear.

As ACC understood the thrust of the Charter SAB member comments and conclusions, the Charter SAB requested the following of the Panel:

The final report must scientifically justify the Panel's endorsement of EPA's position that dioxin causes all cancer mortality.

- The final report must eliminate the lack of clarity in the draft report regarding the threshold and linearity, approaches. Consistent with the 2006 recommendations of the

National Academy of Sciences (NAS), the report must clearly state that best available science demonstrates that the “threshold” is the preferred approach.

- The final report must address the policy-based extrapolation of normal findings in small human studies to the proposition that these normal range findings, although in the lower range of normal, would somehow convert to clinical abnormalities if projected over a much larger population.
- Dr. Rozman is to be consulted and asked if he would elaborate upon the basis for his dissenting opinion. That opinion, and the basis for it, are to be addressed in the body of the final Report, presumably along with the rest of the Panel’s reaction to it

In addition, given the significant amount of discussion on the June Charter SAB conference call of Dr. Rozman’s dissenting opinion, it would be helpful to seek further input from epidemiology experts on the panel. Dr. Rozman will be asked to provide additional explanation of his dissenting opinion, which directly addresses key epidemiology questions. Experts on the Charter SAB, including noted epidemiologist Dr. Patricia Buffler, should be given an opportunity to comment on this additional information.

We also wish to note, as we did in our written comments, that the recently released National Research Council (NRC) IRIS Formaldehyde Report devotes an entire chapter to the need for IRIS reform to address fundamental and systemic methodological flaws in the IRIS assessment process. Despite the NRC’s conclusion that correction of those flaws is essential to the preparation of rigorous, scientifically sound IRIS assessments, and despite the highlighting of those conclusions to the Charter SAB in public comments, the Charter SAB declined to address this recent and highly significant peer review determination. The public comments submitted to the Charter SAB, as well as views expressed by individual Charter SAB members, demonstrate that many of the deficiencies catalogued by the NRC in its formaldehyde report plague EPA’s dioxin assessment as well. Nonetheless, there has been no consideration by the Charter SAB of which ACC is aware as to whether it believes (i) any of the deficiencies noted by the NRC are also present in the draft dioxin reassessment, and (ii) the Panel should be directed to evaluate EPA’s draft dioxin analysis and identify any such deficiencies that EPA needs to address as it finalizes its assessment.

Accordingly, ACC requests that Dr. Jonathan Samat, a principal author of the NRC formaldehyde report and a Charter SAB member, be consulted and asked to provide his views as to whether EPA’s draft dioxin analysis suffers from the same systemic deficiencies that the NRC highlighted in its report. Dr. Samat is in an ideal position to determine quickly whether the final SAB report should recommend that EPA revise its draft analysis to rectify any and all such deficiencies.

Finally, it bears noting that a crucial recommendation made to EPA by two EPA SABs and the NRC on the threshold nature of dioxin’s tumor promotion mode-of-action, now has also been made by the Charter SAB. Given the scientific visibility and far-reaching impact of the IRIS dioxin risk assessment, ACC requests that the Charter SAB remain vigilant and ensure that its recommendations are properly addressed in the SAB’s final report and are fully incorporated into the dioxin risk assessment itself.

If you have any questions, please do not hesitate to contact me (202-249-6709, judith_nordgren@americanchemistry.com) or Jeffrey Sloan (202-249-6710, jeffrey_sloan@americanchemistry.com).

Sincerely,

Judith Nordgren
Managing Director, Chlorine Chemistry Division

cc: Dr. Deborah Swackhammer